

Attorney Docket No.: **UIC0005US.NP**  
Inventors: **Kumar et al.**  
Serial No.: **10/567,958**  
Filing Date: **May 10, 2006**  
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#### **REMARKS**

Claims 12-20 are pending in this application. Claims 15-20 have been withdrawn from consideration. Claims 12-14 have been rejected. Claim 12 has been amended. Claims 21 and 22 have been added. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Election/Restriction Requirement Under 35 U.S.C. §121**

The restriction of the claims into Groups I (claims 12-14) and II (claims 15-20) has been deemed proper and made final. Claims 15-20 have been withdrawn from further consideration as being drawn to non-elected subject matter. Accordingly, Applicants are withdrawing claims 15-20, reserving the right to rejoin the withdrawn subject matter upon allowance of the product claims from which claim 15-20 depend.

#### **II. Rejection of the Claims Under 35 U.S.C. §102/§103**

Claims 12 and 13 have been rejected under 35 U.S.C. 102(e) as being anticipated by McSwiggen et al. (WO 03/070197). It is suggested that McSwiggen et al. disclose siRNA targeted to human TGF $\beta$ RII including those within the size range instantly recited. It is suggested that McSwiggen et al. disclose the use of pharmaceutical carriers and pharmaceutical compositions comprising siRNA targeted to human TGF $\beta$ RII for the treatment of various conditions associated with TGF $\beta$ RII.

Claims 12-14 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al. and Murray et al. (US 20030064944). It is suggested that McSwiggen et al. teach siRNA

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targeted to human TGF $\beta$ RII. It is acknowledged however that McSwiggen et al. do not specifically disclose the use of a "wound healing agent" in their pharmaceutical composition containing siRNA targeted to TGF $\beta$ RII. To compensate for this deficiency, the Examiner suggests that Murray et al. teach the use of antisense compounds which, similar to siRNA, inhibit gene expression of a targeted gene, wherein such antisense compounds inhibit the expression of human TGF $\beta$ RII and are combined with 5-fluorouracil. It is suggested that it would have been obvious to one skilled in the art to substitute the antisense compound of Murray et al. with the siRNA of McSwiggen et al. to inhibit the expression of TGF $\beta$ RII.

Applicants respectfully disagree with these rejections.

To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See *Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

In the instant case, McSwiggen et al. do not provide a single example of a siRNA molecule or single specific target

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region of the disclosed TGF $\beta$ RII sequence set forth in GENBANK Accession No. NM\_003242. While Table II specifies siRNA target sequences present in GENBANK Accession No. NM\_004612.1, which encodes *TGF $\beta$ RI* (see pages 114-117 and Table 1 at page 113) and Table III specifies *TGF $\beta$ RI* target sequences (see page 119), McSwiggen et al. do not provide an enabling disclosure of siRNA molecules that target *TGF $\beta$ RII* and inhibit the expression of the same, or more specifically siRNA molecules that target at least a portion of the coding sequence of the instant SEQ ID NO:159.

In contrast, Applicants disclose a plurality of targets and siRNA molecules for use in inhibiting TGF $\beta$ RII expression. Accordingly, in an earnest effort to advance the prosecution of this application and distinguish the instant invention from the teachings of the cited references, Applicants have amended claim 12 and added claims 21 and 22 to highlight specific portions of the TGF $\beta$ RII coding sequence encompassed within SEQ ID NO:159 and specific siRNA molecules targeting the TGF $\beta$ RII coding sequence of SEQ ID NO:159. Support for this amendment is found at page 5 and Figure 3B of the application.

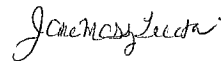
In so far as the specified targets and siRNA molecules are neither taught nor suggested by the McSwiggen et al. or Murray et al., these references can not be held to anticipate or make obvious the subject matter of the claims as currently presented. It is therefore respectfully requested that the rejection of the claims under 35 U.S.C. 102(e) and 103(a) be reconsidered and withdrawn.

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### III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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